Docket No.: HO-P02726US2

## **CLAIMS**

## What is claimed is:

- 1. A method of treating a cardiovascular disease comprising the step of administering to a subject an effective amount of a lactoferrin composition to provide an improvement in the cardiovascular disease in said subject.
- 2. The method of claim 1, wherein the cardiovascular disease is atherosclerosis.
- 3. The method of claim 1, wherein said lactoferrin composition reduces levels of circulating total cholesterol, low density lipoproteins (LDL), very low density lipoproteins (VLDL), or triglycerides in said subject.
- 4. The method of claim 1, wherein said lactoferrin composition increases the levels of circulating high density lipoproteins (HDL) in said subject.
- 5. The method of claim 1, wherein said lactoferrin composition reduces the levels of vascular inflammation in said subject.
- 6. The method of claim 1, wherein said lactoferrin composition reduces circulating C-reactive protein (CRP) in said subject.
- 7. The method of claim 1, wherein said lactoferrin composition reduces the proliferation of vascular smooth muscle cells in said subject.
- 8. The method of claim 1, wherein said lactoferrin composition reduces the vascular spasm or vascular hyper-reactivity in said subject.
- 9. The method of claim 1, wherein said lactoferrin composition promotes endothelial integrity or healing in said subject.
- 10. The method of claim 1, wherein said lactoferrin composition is dispersed in a pharmaceutically acceptable carrier.
- 11. The method of claim 1, wherein said lactoferrin is mammalian lactoferrin.
- 12. The method of claim 11, wherein said lactoferrin is human or bovine.

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- 13. The method of claim 1, wherein said lactoferrin is recombinant lactoferrin.
- 14. The method of claim 1, wherein said lactoferrin composition comprises an N-terminal lactoferrin variant.
- 15. The method of claim 14, wherein the N-terminal lactoferrin variant lacks at least the N-terminal glycine residue.
- 16. The method of claim 15, wherein said N-terminal lactoferrin variant comprises at least 1% to at least 50% of the lactoferrin composition.
- 17. The method of claim 1, wherein said lactoferrin composition is administered parenterally.
- 18. The method of claim 17, wherein parenterally is subcutaneously, intramuscularly, intraperitoneally, intravenously, intraarterially, intramyocardially, transendocardially, transepicardially, or intrathecally.
- 19. The method of claim 1, wherein said lactoferrin composition is administered orally.
- 20. The method of claim 19 further comprising administering an antacid in conjunction with said lactoferrin composition.
- 21. The method of claim 19 further comprising administering the lactoferrin in a delayed release formulation.
- 22. The method of claim 21 where the lactoferrin release occurs in the small intestine.
- 23. The method of claim 21 where the lactoferrin release occurs in the large intestine.
- 24. The method of claim 1, wherein the amount of the lactoferrin that is administered is about 1 ng to about 20 g per day.
- 25. The method of claim 1, wherein the amount of the lactoferrin that is administered is about 0.1 g to about 5 g per day.
- 26. The method of claim 1, wherein said lactoferrin composition reduces the production or activity of pro-inflammatory cytokines.

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27. The method of claim 1 further comprising administering a lactoferrin composition in combination with an anti-cholesterol agent or an anti-inflammatory agent.

- 28. The method of claim 27, wherein the anti-cholesterol agent is selected from the group consisting of cholesterol absorption inhibitors, bile acid sequestrants, nicotinic acid, fibric acids and HMG-coA reductase inhibitors.
- 29. The method of claim 28, wherein the bile acid sequestrants are selected from the group consisting of cholestryramine, cholestipol and colesevalam.
- 30. The method of claim 28, wherein the fibric acids are selected from the group consisting of gemfibrozil, fenofibrate and clofibrate.
- 31. The method of claim 28, wherein the HMG-coA reductase inhibitors are selected from the group consisting of lovastatin, pravastatin, simvastatin, fluvastatin, atorvastatin and cerivastatin.
- 32. A method of modulating atherosclerosis in a subject comprising the step of administering to said subject an effective amount of a lactoferrin composition to modulate atherosclerosis in said subject.
- 33. The method of claim 32, wherein modulating is reducing the incidence of atherosclerosis in said subject.
- 34. The method of claim 32, wherein modulating is reducing the severity of atherosclerosis in said subject.